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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/447,218 | 11/23/99 | ABERG | A 4821-362 |

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| EXAMINER | |
|---|---|
| CRANE, L | |
| **ART UNIT** | **PAPER NUMBER** |
| 1623 | 10 |

**DATE MAILED:** 12/22/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/447,218 | Aberg et al. . |
| **Examiner** | **Group Art Unit** |
| L. E. Crane | 1623 |

***—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ---3--- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

☒ Responsive to communication(s) filed on 04/23/00 (IDS) and 08/23/00 (Amdt C)------.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

**Disposition of Claims**

☒ Claim(s) 34-40 ---------- is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 34-40 ---------- is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119 (a)-(d)**

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

**Attachment(s)**

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). ---8---- ☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

**Office Action Summary**

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

No claims have been cancelled, amended forms of claims **34, 35 and 37-40** have been entered, and no new claims have been added as per the amendment filed August 23, 2000.

Claims **34-40** remain in the case.

Claim(s) **35 asnd 37** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims **35 and 37**, by their use of the term "further comprising, provide for a further limitation of a method of treating allergic reactions by administration of the use of descarbethoxyloratadine (DCL) to treat an allergic reaction. But since the noted claims do not set forth any step, steps or alterations in the method as originally claimed involved in the method of treatment, it is unclear what changes in the method of claim **34** are intended by the incomplete limitations in claims **35 and 37**. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Applicant's arguments with respect to claims **35 and 37** have been considered but are moot in view of the new grounds of rejection.

The subject matter of claim **36** is apparently also related to the incompletely defined limitations now included in claim **35**, but like present

claim **35**, claim **36** does not provide any details concerning how the method of claim **34** is to be modified to deal with an increased susceptibility to cancer of a given host in need of treatment for an allergic reaction. However, because applicant has not effectively addressed the previous grounds of rejection of claim **36**, this claim remains indefinite only for the reasons noted in the previous Office action.

Applicant's arguments filed August 23, 2000 have been fully considered but they are not persuasive.

Applicant has not amended claim **36** in response to the previous Office action and has made no argument for the patentability of claim **36** standing alone in light of the previous Office action. Therefore the previous grounds of rejection have been maintained.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."**

Claims **34-40** are rejected under 35 U.S.C. §103(a) as being unpatentable over Berkow et al. (PTO-892 ref. **R**) in view of Villani et al. '716 (PTO-1449 ref. **AE**).

The instant claims are directed to the treatment of urticaria (aka hives) by the administration of an effective dosage of descarboethoxyloratadine to a patient in need thereof.

Berkow et al. discloses at p. 333, beginning in the third line under "**Treatment**," that " [s]ymptoms [of urticaria] usually can be relieved with an oral [dose of an] antihistamine ... ."

Villani et al. '716 discloses at column 1, lines 39-46 that descarboethoxyloratadine (DCL) and closely related compounds are effective antihistamines with the advantage of low CNS-related side effects, i.e. that DCL and relatives are non-sedative.

The findings that
i) Villani et al.'s teaching that DCL and related compounds are known to be effect antihistamines,
ii) the teaching by applicant that DCL has the expected effect in the treatment of urticaria (hives) as predicted by Berkow et al., and
iii) the failure of applicant to establish any unexpected results,
when taken together establish that the instant combination of references renders the instant claimed subject matter lacking in any patentable distinction in view of the noted prior art.

Therefore, the instant claimed of treating urticaria by the administration of DCL would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

Applicant's arguments filed August 23, 2000 have been fully considered but they are not persuasive.

Applicant argues that the instant rejection in inappropriate because it lacks the requisite reasonable expectation of success. Applicant then proceeds to note that the **Berkow** reference is in part directed to first

generation antihistamines and therefore teaches away from the instant method which relies on a second generation antihistamine. Applicant then alleges that the results disclosed herein are therefore unexpected based on a comparison with the compounds cited in **Berkow**. Examiner respectfully disagrees. Applicant is requested to note that the primary reference (**Villani et al. '716**) both discloses and claims "[a] method of treating an allergic reaction in a mammal ...an anti-allegic effective amount of a compound as defined in claim *1*'" (see Villani et al. at claim *14*. ' DCL is one of the compounds defined in Villani et al. '716 at claim *1*). This conclusion is also supported by examining PTO-892 reference **T**, at column 2 of page 2091, wherein the term "urticaria" is medically defined as "a vascular reaction of the skin characterized by the eruption of pale evanescent wheals, which are associated with severe itching. ... [and wherein] the skin manifestation is an allergic reaction... .[and] *Specific measures:* Antihistaminic drugs often give quick relief."

Applicant then repeats the above argument before concluding that neither Villani or Berkow suggest the treatment of urticaria by administration of DCL. Again applicant is referred to claim *14* of the Villani et al. reference which is directed to the treatment of allergic reactions generally. Urticaria is merely a medical name for the skin reaction of an allergic host to contact with an allergen.

Therefore, examiner concludes that Villani et al. and its assignees appear to have held the instant claimed subject matter since 1987.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. §1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are **(703) 308-4556** and **703-305-3592**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-**308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-**308-1235**.

Art Unit 1623

LECrane:lec
**12/19/00**

GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600